Apollo Spine
Premarket Notification 510(k)
Eclipse Vertebral Spacer
June 4, 2010

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN - 7 2011

Submitter Information

Submitter's Name:	Apollo Spine
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Contact Person:	Christine Santagate, STD Medical
Telephone :	781-828-4400
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Date Prepared:	June 4, 2010
Device Trade Name:	Eclipse Vertebral Spacer-Cervical
Common/Usual Name:	Intervertebral body fusion device
Classification:	21 CFR §888.3080
Class:	II
Product Code(s):	ODP

Predicate Device(s):

- BAK/Cervical (BAK/C®), P980048, Zimmer Spine, Approved 4/20/01
- LDR Spine Cervical Interbody Fusion System, ROI-C, Approved 4/15/09
- SpineCraft ORIO-C Intervertebral Body Fusion Cervical Cage, Approved 10/30/09

Substantial Equivalence:
The Eclipse Vertebral Spacer-Cervical was shown to be substantially equivalent to previously cleared devices and had the same indications for use, design, function, and materials used.

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Device Description:
The Eclipse Vertebral Spacer-Cervical acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Eclipse Vertebral Spacer is manufactured from PEEK, unalloyed titanium, and Ti6Al4V titanium alloy.

Indications:

When used as an Intervertebral Body Fusion System:

The Eclipse Vertebral Spacer System-Cervical is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2 to T1. DDD is defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have completed six weeks of non-operative treatment. The Eclipse Vertebral Spacer System-Cervical implants are to be used with autogenous bone graft. Supplemental fixation is required.

Mechanical Test Data:
The following testing was performed on this device:

- Axial Compression – Static & Dynamic per ASTM F 2077
- Compression-Shear – Static & Dynamic per ASTM F 2077
- Torsion – Static & Dynamic per ASTM F 2077
- Subsidence per ASTM F 2267
- Expulsion per ASTM Draft F04.25.02.02

Conclusion:
ASTM Standards F2077, F2667 and Draft F04.25.02.02 (Expulsion Testing) were adhered to and all applicable requirements were met. Test results demonstrate that the Eclipse Spacer is substantially equivalent to publically available data for the predicate devices and therefore demonstrate its suitability for its intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Apollo Spine
% STD Medical, Inc.
Ms. Christine Santagate
3700 Campus Drive, Suite 105
Newport Beach, CA 92660

Re: K101588
Trade/Device Name: Eclipse Vertebral Spacer System-Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 20, 2010
Received: December 29, 2010

Dear Ms. Santagate:

This letter corrects our substantially equivalent letter of January 7, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

JAN - 7 2011

510(k) Number (if known): K101588

Device Name: Eclipse Vertebral Spacer System

Indications for Use:

The Eclipse Vertebral Spacer System-Cervical is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2 to T1. DDD is defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have completed six weeks of non-operative treatment. The Eclipse Vertebral Spacer System-Cervical implants are to be used with autogenous bone graft. Supplemental fixation is required.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101588